Title:

Filing Date: August 25, 1993

METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND

CELLS THEREOF

Claims 47, 51-52, 55-58 and 60-66 are canceled solely in an attempt to advance the prosecution of the present application, and without prejudice to their further prosecution in an appropriately-filed continuing application.

Claim 68, which is directed to a transgenic maize plant comprising a sucrose synthase gene is supported by claim 67, and at column 4, line 12 of the parent application, Serial No. 565,844, filed August 8, 1990. This earlier filing data is relevant to the arguments below relating to predictability of success.

In the final rejection, the Examiner rejected claims 2-4 and 67 as obvious over commonly-assigned Serial Number 07/508,045, now issued as U.S. Patent No. 5,484,956 or over Goldman et al. (U.S. Patent No. 5,187,073). These rejections are respectfully traversed.

The '956 patent in fact broadly enables the introduction into maize of recombinant DNA, particularly that which is expressible and which can be transmitted to progeny. However, there is nothing in either of these references that would motivate the art to select any one of the presently recited genes for introduction into corn. These references also would not provide a reasonable expectation that expression of any of the recited genes would occur so as to yield an identifiable phenotypic characteristic that would distinguish the transformed plant from the corresponding untransformed plant.

While the '956 patent generally discloses that "[suitable] recombinant DNA for use herein includes [DNA encoding] proteins or antisense RNA transcripts in order to promote increased food values," apart from the dapA gene, the specific disclosure related to genes useful to improve "food or feed value" is directed to "genes encoding proteins that contain high levels of essential amino acids." See, column 8, line 15 through column 9, line 10. The '956 patent exemplifies only the introduction of vectors comprising the hpt, gus, neo and Bt genes into maize. Thus, the art worker in possession of the disclosure of the '956 patent would be motivated to investigate the effects of expression of the dapA gene on lysine levels, or the effects of expression of seed storage protein genes on amino acid profiles of seed. There is nothing in the '956 disclosure which would direct the art worker to attempt to modify grain composition by altering the profiles or levels of fatty acids, starches, sucrose and the like.

Likewise, Goldman et al. (reference is to U.S. Patent No. 6,020,539 (which issued out of a continuation of a continuation of the application which issued as the '073 patent' very generally AMENDMENT UNDER 37 C.F.R. §1.312(a)

Serial Number: 08/113,561

Filing Date: August 25, 1993

le: METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND

Page 3

Dkt: 950.033US1

CELLS THEREOF

disclosed that "the invention allows for the development of strains of Gramineae. The only "heterologous genes" disclosed are either genes native to A. tumefaciens, hpt or glyphosate resistant EPSP synthase. Goldman et al. disclose no other specific genes useful for imparting "altered or superior traits" to maize, and, in fact, fail to demonstrate expression of either hpt or EPSP synthases in maize, much less demonstrate transmission to progeny. Therefore, it is respectfully submitted that one of ordinary skill in the art would, at best, be motivated to investigate the work relating to the introduction of the specific selectable marker genes disclosed by Goldman et al., but would not be led to attempt to express any of the genes recited by claim 67 with any expectation that a grain composition trait could be altered. Put another way, even assuming that the claims of Goldman et al. are in fact broadly enabling, one in possession of the Goldman et al. disclosure as of the effective filing date of the present claims would not consider it to render the invention of claim 67 obvious. This is evidenced, inter alia, by the fact that the PTO repeatedly rejected claims as nonenabled that were broadly drawn to a method of making transgenic corn with any heterologous DNA in parent applications that were filed after the effective filing date of claims 67 or 68. See, for example, Office Action mailed January 27, 1994 in Serial No. 08/016,600 and Office Action mailed December 23, 1994 in Serial No. 08/265,982.

Likewise, while the Lundquist et al. disclosure in fact has been demonstrated to be broadly enabling in the transformation of maize with a wide variety of heterologous genes as of the effective filing data of the present claims, one of ordinary skill in the art would not be motivated to transform maize with the genes recited in claim 67 because they would not have a reasonable expectation of success in expressing these genes at any level. The Examiner is respectfully requested to note that during the prosecution of Serial No. 08/441,073, a continuation of the application that issued as the '956 patent, the Examiner required Applicants to demonstrate the enablement of the specification of the application that issued as the '956 patent, with respect to expression of glyphosate resistant EPSP synthase. (See Examiner interview summary May 24, 1996.) This is a gene specifically disclosed as useful in the specification of the '956 patent. It is respectfully submitted that this skepticism reflects the state of the art subsequent to the effective filing date of the present claims, with respect to specific genes not known to have been expressed in corn.

AMENDMENT UNDER 37 C.F.R. §1.312(a)

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In summary, it is respectfully submitted that neither the '956 patent taken alone or in combination with any of the series of Goldman et al. patents discussed above or with the "state of the art" in August 1993 (or in August 1990 with respect to claim 68), would motivate one of ordinary skill in the art to introduce any of the genes recited in claims 67-68 into maize with a reasonable expectation that they would be expressed as identifiable traits and/or would be transmitted to progeny.

Therefore, it is respectfully submitted that the present claims are in condition for allowance, and notification to that effect is earnestly solicited.

Respectfully submitted,

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Page 4 Dkt: 950.033US1

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